MEMORANDUM

DATE: March 6, 2006

TO: Division of Shellfish Sanitation Staff

FROM: Robert E. Croonenberghs, Ph.D., Director
Division of Shellfish Sanitation

SUBJECT: Shellfish Plants - Procedure - Protocol for Collection of Shellfish for Biotoxin Analysis by FDA

Replaces Working Memo #317

Purpose

The objectives of this protocol are:

1. To establish a uniform methodology for the collection of oysters, hard clams, surf clams and ocean quahogs for biotoxin analysis.

2. To establish clear lines of responsibility for the collection of these samples.

3. To facilitate the collection and shipment of fresh surf clams to the Southeast Regional District FDA laboratory (SRL).

4. To alert the FDA laboratory sufficiently ahead of time when DSS is about to ship samples.

5. To establish a formal record keeping procedure within DSS for samples collected.

Introduction

The Division has entered into a Partnership Agreement with the United States Food and Drug Administration (FDA) to collect and analyze shellfish for biotoxins. Oysters (Crassostrea virginica) and hard clams (Mercenaria mercenaria) will be analyzed for okadaic acid, which causes diarrhetic shellfish poisoning (DSP). Dinoflagellates of the genus *Dinophysis* appear to be increasing in the Chesapeake Bay, and chemical analysis for the toxin is a prudent precautionary step to take. One member of the genus *Dinophysis*, *D. acuminata* has been shown to be a slight toxin producer in the Bay, and other species of this group that occur in the Bay have been proven to be toxic elsewhere in the world (Japan, Europe and Australia). *Dinophysis* tend to initiate growth in the Bay in early spring, and last throughout the summer.

Surf clams (*Spisula solidissima*) and ocean quahogs (*Artica islandica*) will be analyzed for paralytic shellfish poisoning toxin (PSP) and for amnesic shellfish poisoning (ASP) toxin (domoic acid). PSP and ASP tend to be more of a northern, cold water problem and so we will not monitor oysters or hard clams for these toxins. However, the potential exists for phytoplankton from more northern oceanic waters to drift down into the offshore harvest areas for the ocean quahogs and surf clams. Thus, we will sample these species for PSP and ASP toxin analysis.

The Division's responsibility under this agreement is to collect these samples, package them and ship them via overnight delivery to FDA's Southeast Regional Laboratory (SRL).

Responsibilities Under This Agreement

Each field office will assume responsibility for the collection, packaging and shipping of these samples. Collection will occur as follows:

1. The Accomac field office will collect ocean quahog, surf clam, oyster or hard clam samples in January, April, July and October of each year. At least two samples per year, preferably in the cold weather months, shall consist of an offshore species.

2. The White Stone field office will collect oyster or hard clam samples in February, May, August and November of each year. At least three samples per year shall consist of oysters.

3. The Norfolk field office will collect ocean quahog, surf clam, oyster or hard clam samples in March, June, September and December of each year. At least two samples per year, preferably in the cold weather months, shall consist of an offshore species.

4. Oysters and clams shall be from Virginia waters and must have been harvested as recently as possible. Ideally shellstock will be shipped to SERL the same day as harvested.

5. These samples shall be collected and shipped on the third Tuesday of these months.
   - If no shellfish are available at that time, the alternative sampling and shipping date will be the fourth Tuesday of these months.
   - Samples shall be shipped no later than Wednesday.

6. One sample will be collected at the time of sampling.

7. FDA is to be alerted in several ways at two different times:
   a) Two days prior to sampling, the field office will send an email to SRL alerting them that samples will be forthcoming. Copy to Nate Esaw at the Baltimore District Office, since he is now responsible for overseeing FDA's role in this partnership.
      - The email address for SRL is: ORASERLCoordinationTeam@ora.fda.gov
         - include your office phone number on the email so SRL can easily call back if there is a problem for them.
      - The email address for Nate Esaw is nathaniel.esaw@fda.hhs.gov
   b) Once the sample is collected and ready to send out
      i. Preferably email (or fax) the attached "Biotoxin Report Form" to Tamara Champion in Baltimore; Tamara.Champion@fda.hhs.gov, fax (410)779-5707, voice (410)779-5113
      ii. Call SRL and tell them that the sample is indeed on the way.
         - Call one of the following in priority order: Mary (Patti) Ross (404) 253-1200 (x-5411); Roy Roberts (404) 253-1298; or Robert L (Chip) Sellers (404) 253-2269.

8. FDA will issue 12 sample numbers per year (4 for each field office).
    - Use a sample number only once and include one on each sample when sent.
    - This unique sample number will provide tracking in their Field Accomplishment Compliance Tracking System (FACTS) data base and all other data bases.

9. Each field office will maintain a formal file of copies of the Biotoxin Report Form..

10. For shellfish larger than15 cm (6 in), collect a minimum of 12 organisms per sample. For shellfish 10 to 15 cm (4 to 6 in) collect roughly 15 organisms per sample. For shellfish under 10 cm (4 in) collect 30 or more organisms:
    - We are trying to accomplish two goals with sample size:
        - to supply a representative sample of 10 live shellfish
        - to supply enough meat to shuck out to 1.5 pints
    - Since a few shellfish are apt to die in transit, we need to send a minimum of 12 organisms for the largest shellfish:
        - you can adjust the sample size based on size of the shellfish available to meet the 1.5 shucked pint/sample minimum
        - but never send less than 12 organisms per sample

11. These shellfish must be kept in an open (unsealed) plastic bag at all times (*i.e.*, both when first sampled and when shipped). Shellfish shipped in sealed bags overnight suffocate and have arrived at SRL smelling strongly. Therefore, during initial sampling, place the 3 plastic bags in an iced cooler such that the bags do not allow water in on the shellfish. Transport the samples to the field office laboratory, and pack the unsealed bags in the insulated cooler with chill packs for shipping. Ship shellfish on the same day as sampled if possible. Include a copy of the "Biotoxin Report Form" in with the sample.

12. It is the field office's responsibility to obtain and use sufficient coolers and chill packs. Purchase high quality (Igloo type) coolers for use as shipping containers and write the field office's name and address on the inside lid and outside in bold lettering. SRL will periodically return the coolers.

13. Ship samples by overnight delivery to:

Attn: Sample Custodians (VDH/DSS - Clams)
United States Food and Drug Administration
Southeast Regional Laboratory
60 Eighth St. N.E.
Atlanta, GA 30309
(404) 253-1200 ext. 2250 or ext. 2209

14. FDA has agreed to cover all of the costs of mailing these samples and returning the coolers. Nate Esaw will send 12 Federal Express shipping labels and 12 FACTS sample numbers at the beginning of each calendar year to Bob Croonenberghs, who will then distribute them to the three field offices.

BIOTOXIN REPORT FORM

COLLECTION DATE:_____

SHIPPING DATE:_____

TYPE OF SHELLFISH:_____

COMPANY NAME:_____

HARVEST SITE:_____

HARVEST DATE:_____

HARVEST VESSEL:_____

APPROXIMATE SAMPLE WEIGHT:_____

FDA SAMPLE NUMBER:_____

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